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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/885,221	06/20/2001	Alan E. Moorman	C-2805/5 (PHA 4166.5)	3271

321 7590 02/14/2003

SENNIGER POWERS LEAVITT AND ROEDEL
ONE METROPOLITAN SQUARE
16TH FLOOR
ST LOUIS, MO 63102

EXAMINER

KUMAR, SHAILENDRA

ART UNIT	PAPER NUMBER
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1621

DATE MAILED: 02/14/2003

6

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/885,221

Applicant(s)
Moorman et al

Examiner
Shailendra Kumar

Art Unit
1621



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Dec 6, 2002
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 22, 23, and 25-30 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 22, 23, and 25-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 2 6) ☐ Other:

Art Unit: 1621

DETAILED ACTION

This office action is in response to applicants' communication filed in paper # 4 and 5, on 12/6/02.

Claims 1-5, 22, 23, and 25-30 are pending in this application. Claims 6-21 and 24 have been canceled.

Rejection of claims 1-5, 22, 23, and 25-30 under obvious type double patenting over US 5,945,425, is hereby withdrawn, subsequent to submission of acceptable Terminal Disclaimer.

Information Disclosure Statement

1. The information disclosure statement filed 6/20/01 complies with 37 CFR 1.98(a)(3) and has been placed in the application file, and the information referred to therein has been considered.

Claim Rejections - 35 U.S.C. § 103

2. Claims 1-5, 22, 23, and 25-30 are again rejected under 35 U.S.C. 103(a) as being unpatentable over combined teachings of Senn-Biifinger, Ruwart and Lindberg et al, all for the reasons of record as set forth in paper # 3.

Instant claims are directed to a method of treating viral infection in a subject, said method comprising treating the subject with a therapeutically effective amount of sulfur containing

Art Unit: 1621

(H+/K+)ATPase inhibitor, and wherein the virus can be DNA virus or selected from the class of herpetoviridae viruses.

Applicants' arguments were fully considered and were not found convincing.

Applicants argue that Senn-Biifinger disclose the primary utility of the benzimidazoles to inhibit gastric acid secretions, and Ruwart disclose the same class of compounds to be useful as preventing gastrointestinal inflammatory diseases, whereas claim 1 is providing the method of treating a viral infection by administering a sulfur containing compound that inhibits (H+/K+)ATPase. Applicants further allege that no where, the references disclose that their compounds would be effective for treating viral infections. Applicants further allege that Lindberg et al do teach benzimidazoles class of compounds as inhibitor of (H+/K+)ATPase, no where they disclose treatment of viral disease. Furthermore applicants state that claims 3, 22 and 23 are drawn to treatment of DNA viral infection, claims 4 and 25 particularly drawn to treatment of herpetoviridae virus infection, which teachings are absent from any reference. Thus applicants conclude that no prima facie case has been established.

The examiner would like to point out that, Senn-Biifinger, column 1, lines 17-19, and Ruwart, column 1, line 50, expressly teach that benzimidazoles which are structurally similar to those disclosed in the instant specification, are antiviral compounds. The references do not teach that benzimidazole inhibit (H+/K+)ATPase activity. However, Lindberg et al expressly teach that benzimidazoles do inhibit (H+/K+)ATPase activity. Thus given that Senn-Biifinger and Ruwart teach benzimidazoles to be anti viral, and Lindberg expressly teaching that the same

Art Unit: 1621

benzimidazoles are inhibitors of (H⁺/K⁺)ATPase activity, one of ordinary skill in the art would be motivated to use the benzimidazoles having inhibiting property of (H⁺/K⁺)ATPase activity of Lindberg et al, in the treatment of viral infection of Senn-Biifinger and Ruwart, with the reasonable expectation of treating viral infection, absent evidence to the contrary. Applicants' arguments that the reference do not teach DNA virus or treatment of herpetoviridae virus infection, is of little if any probative value inasmuch as the virus of the prior art contemplates all kinds of viruses, absent evidence to the contrary.

It is not relevant that the references make no mention of treatment of infection caused by DNA virus and particularly treatment of herpetoviridae virus infection. Discovery of a new benefit for an old process does not render the old process patentable. In re Woodruff, 919 F. 2d 1575, 1578, 16 USPQ2d 1934, 1946 (Fed.Cir. 1990). The references teach the active agent, the effective amount, and the patient of the claims. Merely because the references did not have applicants' purpose in mind when the drug was administered does not alter the drug's physiological activity. Thus , the Federal circuit stated, that "Where, as here, the result is a necessary consequence of what was deliberately intended, it is of no import that the references did not appreciate the results. " Mehl/Biophile Int'l corp. V. Milgraum, 192 F. 3d 1362, 1366, 52 USPQ2d 1303, 1307(Fed. Cir. 1999). Applicants' compounds contemplate the compounds of the references.

Art Unit: 1621

3. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to S.Kumar whose telephone number is (703)-308-4519. The examiner can normally be reached on Monday to Thursday from 8:00 to 5:30 PM. The examiner can also be reached on alternate .

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter, can be reached on (703) 308-4532. The fax phone number for the organization where this application or proceeding is assigned is (703)-308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)-308-1235.

S. Kumar
2/11/03


SHAIENDRA KUMAR
PRIMARY EXAMINER
GROUP 1200